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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Rebecca Betensky, Ph.D. Doc. 7288. The motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court will deny the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. IVC filters, such as Bard's Simon Nitinol Filter ("SNF"), originally were designed to be implanted permanently. Because some patients need only temporary filters, however, medical device manufacturers such as Bard developed retrievable filters. Bard first marketed a retrievable filter in 2003. Seven different versions of Bard retrievable filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard retrievable filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that the filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

Plaintiffs have identified Dr. Betensky, a biostatistician, as an expert witness regarding risk rates associated with Bard filters. Dr. Betensky is the director of biostatistics programs at Massachusetts General Hospital and Harvard University. She is a faculty member at the Harvard-MIT Division of Health Sciences and Technology, has taught courses in biostatistics at Harvard School of Public Health, and has authored more than 200 peer-reviewed articles related to biostatistics. *See* Doc. 7818 at 4 n.4.

In this MDL, Dr. Betensky opines generally that there is a higher risk of adverse events for Bard's retrievable IVC filters than for its permanent SNF. Doc. 7290. Dr. Betensky relied on sales information provided by Bard and adverse event reports extracted from the MAUDE database maintained by the Food and Drug Administration ("FDA").[1] Dr. Betensky compared, over multiple time periods, the proportion of adverse event reports for each Bard retrievable filter relative to sales, to the proportion of adverse event reports for the SNF over sales. *Id.* at 2. She calculated a "reporting risk ratio" ("RRR") as the ratio of the reporting risk for each retrievable filter to that of the SNF,

[1] The MAUDE database houses adverse event reports submitted to the FDA by medical device manufacturers, hospitals and healthcare professionals, and patients and consumers. *See FDA, MAUDE – Manufacture and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last updated Dec. 31, 2017; last visited Jan. 16, 2018). Reporting by patients and consumers is voluntary, but manufacturers and hospitals must submit reports when they become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury. *See id.*

using this equation: RRR = $(x_1/n_1)/(x_2/n_2)$.[2] The RRR is then used as an estimate of the actual risk ratio ("RR") for the various filters. An RRR value larger than 1 suggests a higher RR for the retrievable filters than for the SNF. *Id.* at 4. Dr. Betensky found that for each Bard retrievable filter, there were statistically significant increased RRRs for adverse events such as death due to filter embolization and filter fracture, migration, perforation, or tilt. *Id.* at 3, 8-12, 15.

Defendants challenge Dr. Betensky's opinions on several grounds. Defendants contend that she applied unfounded assumptions in her calculations, resulting in biased opinions that may not reflect an actual increased risk for retrievable filters. Defendants further contend that the opinions are flawed because Dr. Betensky failed to consider potential adverse events from the first ten years the SNF was on the market, or rule out alternative explanations for the increased risk she estimated. Finally, Defendants contend that the opinions are based solely on an improper comparison of anecdotal adverse event reports contrary to express guidance from the FDA. Doc. 7288 at 2.[3] Plaintiffs oppose the motion, arguing that Dr. Betensky is a highly-qualified expert who considered all available data and used a reliable methodology to form her opinions. Doc. 7818. For reasons stated below, the Court finds that Defendants' criticisms, to the extent valid, go the weight to be afforded the opinions, not their admissibility.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods

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[2] In the equation, x_1 and n_1 denote, respectively, the number of adverse event reports and sales for the retrievable filter, while x_2 and n_2 denote the same information for the SNF.

[3] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Discussion.

A. Assumptions About Adverse Event Reporting.

Dr. Betensky's expert report acknowledges and discusses potential limitations in her analysis. Doc. 7290 at 12-14. These include the possibility that adverse events were underreported for one or more of the devices at issue. Dr. Betensky found that while the RRRs she calculated may involve some degree of underreporting, which makes them "imperfect estimates of the actual risk ratios," there is strong evidence that actual risk ratios are higher for Bard retrievable filters than for the SNF. *Id.* at 13. Dr. Betensky explained her reasoning as follows:

> [A]dverse events are generally considered to be underreported to the databases, and potentially differentially by severity of adverse event and by drug or medical device. . . . It is important to recognize that underreporting in and of itself is not problematic. Rather, differential underreporting of the higher risk device is what leads to bias. And even if there was differential underreporting of the higher risk device, given the variation in reporting relative risks across adverse events, the differential reporting would have had to have been highly variable across adverse events. This does not seem plausible given the severity of the adverse events considered. Given the magnitude of the RRR's, and their variability across adverse events, it seems implausible that differential underreporting by filter could fully explain the deviation of the observed RRR's from 1.

Id. at 12. Dr. Betensky further explained that if Bard "believed that there truly was no elevation in risk associated with Recovery due to SNF, but that all of the signals of elevated reporting risk were due to differential underreporting, it seems likely that they would have increased their monitoring and corrected this problem, especially if underreporting of SNF were due to decreased detection due to its permanence." *Id.* at 13.

Dr. Betensky considered and addressed the possible influence of the Weber effect, which results from increased reporting soon after the launch of a new drug or device. *Id.* at 14. She concluded that the Weber effect does not appear to be at work in the data she analyzed because "the RRR's mostly increase over time." *Id.*

Dr. Betensky further considered whether the incidence of adverse event reporting could have been influenced by publicity, a phenomenon known as the "notoriety effect" or "stimulated reporting." *Id.* She found that the only possible cause of such an effect would be an FDA warning letter about Bard filters, but concluded that the letter did not affect the data she used because the letter was issued in 2015 and the data she used ended in 2014. *Id.* at 2, 14.

Defendants argue that Dr. Betensky's assumptions about adverse event reporting are unreliable because she is not a doctor or an expert in any scientific field other than statistics, and did not collaborate with a medical expert. Doc. 7288 at 8-11. Defendants base this argument on the following assertion: "Determining whether or not assumptions about detection and reporting of adverse events in retrievable and permanent filters are 'plausible' requires an expert understanding of these complex medical devices and their uses." *Id.* at 8. But Defendants provide no citation for this assertion – from their own statistical expert, medical literature, or case law – and it is not apparent to the Court that the assertion is correct.

Dr. Betensky is a highly trained and qualified expert in *bio*statistics, and, as she testified, has "25 years of experience as a Ph.D.-level statistician who has collaborated extensively with investigators in the medical field." *Id.* at 9. The Court cannot conclude that she is unqualified to make reasonable assumptions in her statistical analyses. Dr.

Betensky explained her assumptions, acknowledged their shortcomings, and engaged in sensitivity and other statistical inquiries to test their validity. Doc. 7290 at 12-15. Her opinions are not, as Defendants assert, based solely on "her *ipse dixit*." *Id.* at 2, 11 (citing *G.E. v. Joiner*, 522 U.S. 136, 146 (1997)). This "is not a case where 'there is simply too great an analytical gap between the data and the opinion proffered.'" *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489793, at *7 (S.D. Fla. Feb. 24, 2010) (quoting *Joiner*, 522 U.S. at 146). If Defendants believe Dr. Betensky's assumptions are incorrect (Doc. 7288-3 at 11-12), they can make that assertion through their own statistical expert, Dr. Ronald Thisted (Doc. 8175-4), and can cross examine Dr. Betensky.

Each side has presented a highly qualified statistical expert to opine on the available data about Bard IVC filter failure rates. Dr. Betensky readily acknowledges the assumptions used in her analysis and explains why she believes they are reasonable. She also acknowledges the shortcomings in available data, and admits that she can develop only an estimate of filter risks. But she explains carefully why she believes her estimates are reliable, using statistical techniques to test the estimates and her assumptions. Bard's expert, Dr. Thisted, reaches different conclusions, and carefully explains why.

The Court concludes that this testimony, from two well-qualified experts in statistics, addressing the only data available on comparative risk rates of Bard IVC filters, is sufficiently reliable to satisfy Rule 702 and *Daubert*. "It is not the job of the court to insure that the evidence heard by the jury is error-free," but to insure that it is sufficiently reliable to be considered by the jury. *Southwire Co. v. J.P. Morgan Chase & Co.*, 528 F. Supp. 2d 908, 928 (W.D. Wis. 2007); *see Trasylol*, 2010 WL 1489793, at *7 (the court "must be careful not to conflate questions of admissibility of expert testimony with the weight appropriately to be accorded to such testimony by the fact finder"). Applying the factors identified in Rule 702, the Court finds that Dr. Betensky's evidence meets this standard. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014, 1997

WL 230818, at *8 (E.D. Pa. May 5, 1997) (noting that "there is no such thing as a perfect epidemiological study"); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 1230, 1240 (W.D. Wash. 2003) ("Because the court finds the methodology scientifically sound, any flaws that might exist go to the weight afforded the [study], not its admissibility.").

B. Adverse Events for the SNF and Alternative Explanations.

Defendants argue that Dr. Betensky's analysis is fatally flawed because she considered adverse event reports and sales data for each retrievable filter starting at product launch, but considered no data for the first ten years the SNF was on the market (1990-2000). Doc. 7288 at 11. This omission is particularly egregious, Defendants contend, given that, under the Weber effect, increased reporting can be observed soon after product launch. *Id.* at 11-12. Defendants claim that had Dr. Betensky considered the missing data, she may not have estimated any increased risk in reporting for retrievable filters. *Id.* at 12. Defendants also argue that Dr. Betensky failed to account for differences between retrievable filters and the SNF in terms of detecting asymptomatic adverse events. *Id.* at 12-13.

Defendants argue that pre-2000 SNF data were available to Dr. Betensky on specific spreadsheets Defendants produced to Plaintiffs. Doc. 8221 at 5-6. Significantly, however, Defendants make no attempt to show that the data would have altered Dr. Betensky's conclusions. They make no calculations with the data. Defendants speak only in terms of possibilities, asserting that it is "entirely possible" that data from the first decade of SNF would have altered her conclusions. Docs. 7288 at 12, 8221 at 3. The Court cannot conclude that Dr. Betensky's opinions are unreliable on the basis of mere possibilities. The Court agrees with Plaintiffs that this argument is suitable for cross examination at trial, not for exclusion under Rule 702. Doc. 7818 at 14.

C. Anecdotal Adverse Event Reports.

Defendants contend that Dr. Betensky's opinions are inadmissible because they are based on anecdotal adverse event reports that were made either directly to Bard or

that Bard retrieved from the MAUDE database. Doc. 7288 at 13. Reliance on MAUDE data is problematic, Defendants claim, because the "database is a 'passive surveillance system [that] has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data.'" *Id.* at 13-14; *see* Doc. 288-5 at 2. Defendants note that the FDA itself has cautioned that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices" (Doc. 7288-4 at 2), and has suggested, in the context of pharmaceutical drugs, that "comparison of two or more reporting rates be viewed with extreme caution" (Doc. 7288-6 at 15). *Id.* at 15-16.

Plaintiffs counter that Dr. Betensky did not use MAUDE data, but relied instead on Bard's own internal adverse event and sales data which Bard witnesses have confirmed to be complete, accurate, and reliable. Doc. 7818 at 5-7. Plaintiffs also note that Bard relies on the same data, the FDA recommends that manufacturers use such data to conduct reporting rate analyses, and implanting physicians have published similar analyses of IVC filters. *Id.* at 4-10. Plaintiffs also assert that other lines of evidence support Dr. Betensky's opinion that there is a higher risk of adverse events for Bard's retrievable IVC filters than for the SNF. *Id.* at 10-12.

The Court is persuaded by Plaintiffs' arguments. Dr. Betensky used the only available evidence on Bard filter failure rates – evidence that Bard compiled internally and through MAUDE, and that Bard used internally to make failure rate comparisons. Of course, the fact that this is the only available evidence does not mean that opinions based on it must be admitted; unreliable evidence should not be admitted solely because other evidence cannot be obtained. But Dr. Betensky readily concedes the limitations in the data she used and openly confirms that she has developed an estimate of failure rates, not completely accurate failure rates. She explains, as an expert biostatistician, why her estimates nonetheless reliably suggest that Bard's retrievable filters fail more often than the SNF.

The Court cannot conclude that statisticians should be permitted to testify only when they can derive rock-solid truth. In fact, statisticians would not been needed if such truth was discernable. Statisticians deal in probabilities, trends, and mathematically supported inferences. The Court finds that Dr. Betensky is eminently qualified to provide such opinions, that she does not overstate her findings, that she clearly explains the basis for her assumptions and conclusions, and that the jury should be permitted to hear and evaluate her opinions in light of Defendants' criticisms and counter-expert.

"Under *Daubert*, an expert need not base his or her opinion on the best possible evidence, regardless of availability, but upon 'good grounds based on what is known.'" *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 178 (S.D.N.Y. 2009) (quoting *Daubert*, 509 U.S. at 590). And *Daubert* makes clear that "disputes about the facts underlying an expert's opinions are best addressed through the adversarial process and then by the jury as the ultimate fact-finder." *In re Levaquin Prods. Liab. Litig.*, MDL No. 08-1943 (JRT), 2010 WL 8399942, at *11 (D. Minn. Nov. 4, 2010) (citing *Daubert*, 509 U.S. at 595-96).

Defendants cite *In re Accutane Products Liability Litigation*, 511 F. Supp. 2d 1288, 1298 (M.D. Fla. 2007), which found an expert's reliance on adverse event reports "unreliable as proof of causation because, in general, the events were not observed in such a way as to rule out coincidence or other potential causes." But Dr. Betensky does not present a causation opinion.[4]

[4] The other cases cited by Defendants address either causation opinions or those based on clearly unreliable evidence. *See Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) (anecdotal case reports of patients suffering injuries after taking prescription drug "did not by themselves provide reliable proof of causation"); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999) (finding anecdotal studies used to support medical causation unreliable "in the face of controlled, population-based epidemiological studies which find otherwise"); *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1165 (S.D. Fla. 1996) (excluding causation opinion of pharmacologist who "did not rely on the actual case reports, but only on secondary authorities summarizing the primary clinical findings"); *In re Denture Cream Prods. Liab. Litig.*, No. 09-2051-MD, 2015 WL 392021, at *24 (S.D. Fla. Jan. 28, 2015) (finding the expert's summary of a collection of case reports unreliable where it involved "layers of unsupportable estimations and approximations added to [an] already shaky foundation").

Other courts have noted that adverse event reports, including reports from the MAUDE database, may be used for opinions other than causation. *See Tillman v. C. R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1332 (M.D. Fla. 2015) (allowing opinion in Bard IVC filter case based on MAUDE data); *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, at *11 (N.D. Ohio May 4, 2010) (allowing expert testimony based in part on adverse event reports where the reports were relied on by the FDA in reviewing relative risk, and noting that the defendant was "free to cross-examine the . . . experts regarding the flaws in adverse event reporting"); *Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-CV-00602, 2015 WL 7888387, at *5-7 (S.D. Ohio Dec. 4, 2015) (considering on summary judgment expert testimony based in part on MAUDE data where the expert acknowledged that there are limitations to the data); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 2436, 2016 WL 3854534, at *26 (E.D. Pa. July 14, 2016) ("No study is perfect nor every piece of data entirely accurate. Any flaws in the [expert's] analysis should be brought out on cross-examination[.]").[5]

IT IS ORDERED that Defendants' motion to exclude the opinions of Rebecca Betensky, Ph.D (Doc. 7288) is **denied**.

Dated this 22nd day of January, 2018.

David G. Campbell
United States District Judge

[5] Because Defendants will have a full opportunity to cross examine Dr. Betensky and present their own statistical expert, the Court does not agree that admitting Dr. Betensky's opinions will be unfairly prejudicial under Rule 403. Doc. 7288 at 17.